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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,395	08/14/2003	Michael S.H. Chu	MIY-P01-024	9490
7590	07/29/2008		EXAMINER RYCKMAN, MELISSA K	
Patent Group Ropes & Gray LLP One International Place Boston, MA 02110			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 07/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,395	CHU ET AL.	
	Examiner	Art Unit	
	MELISSA RYCKMAN	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 May 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14, 16, 17, 19, 20, 22-33 and 36-40 is/are pending in the application.

4a) Of the above claim(s) 25-33 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-14, 16, 17, 19, 20, 22-24 and 36-40 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/24/07, 5/25/07</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/25/07 has been entered.

Applicant's election with traverse of Group 1 in the reply filed on 5/22/08 is acknowledged. The traversal is on the ground(s) that there is no burden to the examiner. The examiners position is this is not found persuasive because, a new examiner is acting on the case and deems it a burden to the new examiner, as group I can be used differently than described in invention II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 36-38 recites the limitation "the implant" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 37 and 40 are recites the limitation "the substantially straight section" in the claims. This is unclear if the substantially straight section is referring to the straight section of the shaft or the pusher tube.

Claims 1,10,25 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not include the pusher tube is adapted to form an interface with the implant along the substantially straight section of the proximal end of the shaft.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesy et al. (US 5334185).

Regarding Claim 1, Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising; a handle (12), a shaft having proximal and distal ends (20) and attached to the handle at the proximal end (20a), the distal end having a curved section and the proximal end having a

substantially straight section, a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along the substantially straight section of the proximal end of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push an implant into the anatomical site, wherein the pusher tube (22) is adapted to form an interface with the implant along the substantially straight section of the proximal end of the shaft (capable of being used with an implant that forms an interface with the straight section of the proximal end of the shaft, the applicant is not distinctly claiming the implant).

Regarding Claim 2, Giesy teaches the delivery device of claim 1, wherein the pusher tube (22) and the pushing mechanism (24) are integrated into a single assembly.

Regarding Claim 3, Giesy teaches the delivery device of claim 1, wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30).

Regarding claim 4, Giesy teaches the delivery device of claim 3, wherein the handle includes a first stop (14a) located at a proximal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (24) located at a distal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.

Regarding Claim 7, Giesy teaches the delivery device of claim 3, wherein the first axially extending tongue includes a first projection (24i located at a distal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.

Regarding Claim 8, Giesy teaches the delivery device of claim 1, wherein the pushing mechanism (24) slidably interfits (25) over the shaft.(20) and includes a pusher button (24) for actuating the pushing mechanism.

Regarding Claim 9, Giesy teaches the delivery device of claim 1, wherein the pusher button (24) includes a reduced diameter portion for accommodating a finger of a medical operator (upper portion of button 24 tapers).

Regarding claim 36, Giesy teaches the device of claim 1, the pusher tube remains proximal to the curved section (Fig. 1).

Regarding claim 38, Giesy teaches the device of claim 1, the pusher tube forms a non-overlapping connection interface with the implant (capable of being used with an implant that connects to the pusher tube as described, the applicant has not distinctly claimed an implant).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-13, 17, 19, 20, 22-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (US 6960160) in view Hart (US 5,626,614), and further in view of Giesy.

Browning teaches the following:

- an implant (10) for being delivered to an anatomical site in the body of a patient
- a handle (50)
- an implant comprising a sling assembly (20) having first and second ends
- sling assembly includes a first guide tube (30) attached to the first end and a second guide tube (30) attached to the second end, and each of the first and second guide tubes are sized for slidably interfitting over a distal end of the shaft (50)
- shaft (50) has a conical tip (fig. 8c) at the distal end and at least one end of the first and second guide tubes is tapered (upper portion in fig. 8a) to accommodate the conical tip.
- first and second guide tubes (30) are sized for interfitting, alternately, and one at a time, over the shaft (50) and abutting a distal end of the pusher tube (fig. 4).
- first guide tube (30) has proximal and distal ends and attaches at the proximal end to the first end of the sling assembly and slidably interfits over the shaft, proximal end first.

Browning fails to disclose a pusher tube slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube

distally along a portion of the shaft to deliver an implant to an anatomical site, and wherein the pusher tube and the pushing mechanism are integrated into a single assembly.

Hart teaches an implant introducer comprising a pusher tube (65) slidably fitted over the shaft (54) and extending from the handle (61) distally along a portion of the shaft, and a pushing mechanism (63) operatively interconnected with the handle (61) for actuating the pusher tube (65) distally along a portion of the shaft and wherein the pusher tube and the pushing mechanism are integrated into a single assembly, wherein a pusher button (63) actuates the pushing mechanism and includes a reduced diameter portion for accommodating a finger of a medical operator to deliver an implant (12) to an anatomical site in order to effectively eject the implant off of the shaft. The pusher tube (65) is adapted to form an interface with the implant (12) along the substantially straight section of the proximal end of the shaft (Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with the pusher assembly of Hart in order to effectively eject the implant off of the shaft.

The combination of Browning and Hart fails to teach the following:

- wherein the distal end of the shaft has a curved section and the proximal end of the shaft has a substantially straight section
- wherein the handle includes a first axially extending recess and the pushing mechanism includes a first axially extending tongue for slidably interfitting with the first axially extending recess

- wherein the handle includes a first stop located at a distal end of the first axially extending recess and the first axially extending tongue includes a projection located at a proximal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.
- wherein the first axially extending tongue includes a first projection located at a distal end for engaging with a proximal end of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.
- wherein the pusher tube remains proximal to the curved section

Regarding the limitation wherein the distal end of the shaft has a curved section and the proximal end of the shaft has a substantially straight section, Giesy teaches a device wherein the distal end of the shaft has a curved section and the proximal end of the shaft has a substantially straight section in order to provide an instrument whose shape generally conforms to that of the urethral sound to facilitate placement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Browning and Hart as taught by Giesy in order to provide an instrument whose shape generally conforms to that of the urethral sound to facilitate placement. Regarding the limitations of the handle configuration, the combination of Browning and Hart does teach a handle having a sliding pusher button (Hart, 63), but does not explicitly disclose the mechanism of the handle. Giesy teaches a handle with a pusher mechanism wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30), wherein the handle includes a first

stop (14b) located at a distal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (26) located at a proximal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle and wherein the first axially extending tongue includes a first projection (26) located at a proximal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle, the pusher tube remains proximal to the curved section (Fig. 1)

It would have been an obvious matter of design choice to explicitly describe the handle mechanism of Hart to meet these limitation since it appears that the handle of Hart must have a recess to receive a projection from pusher button 63 in order to actuate pusher 65, and further applicant has not disclosed that this configuration provides any advantage over another configuration, and it appears that the pusher button mechanism of the combination of Browning and Hart performs the task of actuating the pusher equally well as that of the present application.

Claims 5, 6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy and the combination of Browning, Hart and Giesy, and further as a matter of design choice.

Giesy and the combination of Browning, Hart and Giesy teach all limitations of preceding dependent claims 1, 3, 4, 10, 12 and 13 as previously described but fails to disclose wherein the handle includes a second axially extending recess substantially

parallel to the first axially extending recess, and the pushing mechanism includes a second axially extending tongue for slidably interfitting with the second axially extending recess and a second stop associated therewith. Giesy discloses a first set of recess, tongue and stop for the purpose of actuating the slideable tube. Since the applicant has not disclosed that adding a second set of actuating parts solves any stated purpose, and it appears that a single set of actuating parts as disclosed by Giesy would perform equally well as if a second set of actuating parts were present. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Giesy with a second set of actuation parts since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Response to Arguments

Applicant's arguments filed 4/9/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Giesy does not teach the limitations as newly amended including "the pusher tube is adapted to form an interface with the implant"

The examiners position is the applicant has not distinctly claimed the implant in claim 1, therefore the pusher tube is capable of being used with an implant that forms an interface as described in the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

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